European Medicines Agency

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EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

COMTESS

EPAR summary for the public

This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the studies performed, to reach their recommendations on how to use the medicine.
If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis of the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Comtess?

Comtess is a medicine that contains the active substance entacapone. It is available as brown-orange tablets (200 mg).

What is Comtess used for?

Comtess is used to treat patients with Parkinson's disease. Parkinson's disease is a progressive brain disorder that causes shaking, slow movement and muscle stiffness. Comtess is used together with levodopa (either a combination of levodopa and benserazide or a combination of levodopa and carbidopa) when the patient is having 'fluctuations' towards the end of the period between two doses of their medication. Fluctuations happen when the effects of the medication wear off and symptoms re-emerge. They are linked with a reduction in the effects of levodopa, when the patient experiences sudden switches between being 'on' and able to move, and being 'off' and having difficulties moving about. Comtess is used when these fluctuations cannot be treated with the standard levodopa-containing combination alone.
The medicine can only be obtained with a prescription.

How is Comtess used?

Comtess is only used in combination either with levodopa and benserazide or with levodopa and carbidopa. It is taken as one tablet with each dose of the other medicine, up to a maximum of 10 tablets a day. It can be taken with or without food. When patients first add Comtess to their existing medication, they may need to take a lower daily dose of levodopa, either by changing how often they take it, or by reducing the amount of levodopa taken in each dose. Comtess can only be used with conventional combinations of levodopa. It should not be used with combinations that are 'modified release' (when the levodopa is released slowly over a few hours).

How does Comtess work?

In patients with Parkinson's disease, the cells in the brain that produce the neurotransmitter dopamine begin to die and the amount of dopamine in the brain decreases. The patients then lose their ability to control their movements reliably. The active substance in Comtess, entacapone, works to restore the levels of dopamine in the parts of the brain that control movement and co-ordination. It only works when it is taken with levodopa, a copy of the neurotransmitter dopamine that can be taken by mouth. Entacapone blocks an enzyme that is involved in the breakdown of levodopa in the body called

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catechol-O-methyl transferase (COMT). As a result, levodopa remains active for longer. This helps to improve the symptoms of Parkinson's disease, such as stiffness and slowness of movement.

How has Comtess been studied?
Comtess has been studied in a total of 376 patients with Parkinson's disease, in two six-month studies that measured the effects of adding Comtess or placebo (a dummy medicine) to the patient's combination of levodopa and carbidopa or levodopa and benserazide. The main measure of effectiveness was the time spent in the 'on' state (the time when levodopa is controlling the symptoms of Parkinson's disease) after the first levodopa dose of the morning in the first study, and over one day in the second study.

What benefit has Comtess shown during the studies?
Comtess was more effective than placebo in both studies. In the first study, adding Comtess increased the 'on' time by 1 hour and 18 minutes more than adding placebo. In the second study, the 'on' time was increased by 35 minutes compared with placebo.

What is the risk associated with Comtess?
The most common side effects with Comtess (seen in between 1 and 10 patients in 100) are dyskinesia (uncontrollable movements), nausea (feeling sick) and harmless urine discoloration. For the full list of all side effects reported with Comtess, see the Package Leaflet.
Comtess should not be used in people who may be hypersensitive (allergic) to entacapone or any of the other ingredients. Comtess should not be used in patients with:

- liver disease;
- phaeochromocytoma (a tumour of the adrenal gland);
- a history of neuroleptic malignant syndrome (a dangerous nervous system disorder usually caused by antipsychotic medicines) or rhabdomyolysis (breakdown of muscle fibres).

Comtess should not be used together with other medicines that belong to the group 'monoamine oxidase inhibitors' (a type of antidepressant). See the Summary of Product Characteristics (also part of the EPAR) for full details.

Why has Comtess been approved?
The Committee for Medicinal Products for Human Use (CHMP) decided that Comtess's benefits are greater than its risks as an adjunct to standard preparations of levodopa/benserazide or levodopa/carbidopa for use in patients with Parkinson's disease and end-of-dose motor fluctuations, who cannot be stabilised on those combinations. The Committee recommended that Comtess be given marketing authorisation.

Other information about Comtess:
The European Commission granted a marketing authorisation valid throughout the European Union for Comtess on 16 September 1998. The marketing authorisation was renewed on 16 September 2003 and on 16 September 2008. The marketing authorisation holder is Orion Corporation.

The full EPAR for Comtess is available here.

This summary was last updated in 08-2008.